

Amendment #1 to RFP-NIH-NIAID-DIR-04-01
"Operation of a Facility for the Testing of Malaria Vaccines in Adult Human Subjects"

Amendment to Solicitation No.: NIH-NIAID-DIR-04-01

Amendment No.: 1

Issue Date: October 14, 2003

Effective Date: October 14, 2003

Proposal Due Date: December 16, 2003, at 4:00 P.M. local time

Issued By: Thomas P. Hastings
Contracting Officer
NIH/NIAID
Contract Management Branch
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Bethesda, Maryland 20892-7612

Point of Contact: Donald E. Collie, Contract Specialist
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Name and Address of Offeror: To All Potential Offerors

The above numbered solicitation is amended as set forth below. The hour and date specified for receipt of proposals **HAS NOT** been extended. Offerors must acknowledge receipt of this amendment. Failure to receive your acknowledgement of this amendment may result in the rejection of your offer. This amendment shall be acknowledged in the following manner:

- By acknowledging receipt of this amendment on each copy of the offer submitted.

RFP No. NIH-NIAID-DIR-04-01 is amended as follows:

- **The following are a list of questions and answers for this solicitation:**

1. Will the contractor or MVDU be responsible for the Biostatistics?

Answer: The contractor.

2. Will the contractor or MVDU be responsible for the Data Management?

Answer: The contractor.

3. Section 4.e., Statement of Work. Will the contractor or MVDU perform the assays for total protein concentration for all formulations and estimate the unbound protein concentration in alum suspensions? In summary, will the contractor mix the formulations, and the MVDU do the assays?

Answer: The MVDU will be responsible for all quality control (QC) on formulations including any point of injection formulations. The contractor may be called to mix formulations, but MVDU will do the QC.

4. Section 4.f., Statement of Work. “Provides facilities to enable MVDU staff.....etc.” I assume the space will be supplied by the contractor but the equipment will be supplied by MVDU?

Answer: Contractor supplies space. MVDU will supply the equipment.

5. Please tell us what GLP lab standard is required for antibody assays?

Answer: The GLP lab standard used should follow the code of Federal Regulations (CFR) followed by the FDA.